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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,647	08/01/2005	Johan Andersson	026220-00064	7625

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EXAMINER
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KOSACK, JOSEPH R

ART UNIT	PAPER NUMBER
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1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/05/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/527,647

Applicant(s)

ANDERSSON ET AL.

Examiner

Joseph Kosack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,6-22,24,26,32,34,35 and 39-49 is/are pending in the application.
- 4a) Of the above claim(s) 26,32,34,35 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6-22,24 and 39-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/14/2005 & 8/1/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1, 6-22, 24, 26, 32, 34-35, and 39-49 are pending in the instant application.

#### ***Amendments***

The amendment to the claims filed on November 14, 2006 has been acknowledged and has been entered into the record.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I (claims 1, 6-22, and 24 (in part)) in the reply filed on November 14, 2006 is acknowledged. The traversal is on the ground(s) that the inventions are related by the reagents used and that no lack of unity was made during the international phase. This is not found persuasive because an obviousness rejection can be made on the instant process (lack of inventive step) and that lack of unity is reevaluated at each stage of an application, whether international or national stage.

The requirement is still deemed proper and is therefore made FINAL.

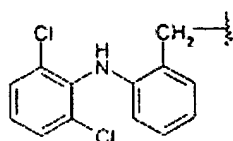
#### ***Status of the Claims***

Claims 1, 6-22, 24, 26, 32, 34-35, and 39-49 are pending in the instant application. Claims 1, 6-22, 24 and 39-48 (all in part) and 26, 32, 34-35, and 49 (all in full) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in the structure and element and

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would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Pursuant to Applicant's election of a species, the scope of the invention will be limited to methods of making compounds with the following substitutions of the base structure  $ML_{T1}A_{T2}-COO-X-ONO_m$  where:



- $ML_{T1}A_{T2}$  is ;
- X is linear  $-(CH_2)_{w1}-$  or  $-(CH_2)_{w2}O(CH_2)_{w3}-$ ;
- m is 2;
- w1, w2, and w3 are as defined.

As a result of the election and the corresponding scope of the invention defined supra, the remaining subject matter of Claims 1, 6-22, 24 and 39-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions.

### ***Priority***

The claim to priority as a 371 filing of PCT/SE03/01465 filed September 18, 2003 which claims priority to SE 0301476-8 filed May 20, 2003 and SE 0202801-7 filed September 20, 2002 is acknowledged in the instant application.

### ***Information Disclosure Statement***

The Information Disclosure Statements filed on March 14, 2005 and September 1, 2005 have been considered fully by the Examiner.

### ***Specification***

The disclosure is objected to because of the following informalities: no brief description or detailed description of the drawing is in the specification.

Appropriate correction is required.

### ***Claim Objections***

Claims 1, 6-22, 24 and 39-48 are objected to for containing elected and non-elected subject matter. The elected subject matter have been identified supra.

Claim 9 objected to because of the following informalities: missing a comma between perchloric acid and polystyrene sulphonic acids. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-41 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims contain new matter as it cannot be determined from reading the areas alleged for support (Examples 1-3) where the exact temperatures of reaction come from. Applicant should either delete the claims or

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point out specifically where each and every aspect of the claim has support from the original filing.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6-22, 24 and 39-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Del Soldato et al. (WO 95/30641 A1) in view of Lai et al. (USPN 6,355,666), Cainelli et al. (*J. Chem. Soc. Perkin Trans.*, 1987, 2637-2642) and Hwu et al. (*Synthesis*, 1994, 471-474).

The instant application is drawn to a process for making a nitrooxy linked diclofenac. The process comprises reacting diclofenac with a diol-linker, reacting the resulting product with an alkylsulfonyl source, and reacting that product with an alkali nitrate to yield the final product. Exact details on solvents, purification, and other parameters are provided in the claims.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Del Soldato et al. teach the reaction of diclofenac with a dihalolinker (either alkyl or ether linker) with further reaction with silver nitrate to yield the nitrooxy-linked diclofenac. See pages 40-51.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

Del Soldato et al. do not teach the reaction of diclofenac with a glycol linker, reaction of that product with an alkylsulfonyl source, or reaction with an alkali nitrate. Also, the exact details of solvents, purification, and other parameters provided in dependent claims are not addressed.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

Lai et al. teach the reaction of NSAID's, such as diclofenac and naproxen, with glycolic linkers in chloroform and toluenesulfonic acid. See columns 9-15.

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Cainelli et al. teach the reaction of a hydroxyl group with mesityl chloride in triethylamine and toluene to yield a methanesulfonyl compound. Further reaction with tetrabutylammonium nitrate yields a nitrooxy compound. See page 2641, Compounds 8-11.

Hwu et al. teaches using a mixture of tetrabutylammonium nitrate and sodium nitrate for the nitration step. See page 472.

The remaining differences in solvents, acids, crystallization, and temperature are deemed to be routine experimentation. The above items are either routinely modified in the art to affect yield and crude purity of a reaction (solvent, acid, and temperature) or is a step that is routinely performed to purify a compound (crystallization.) "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the reaction scheme of Del Soldato et al. with the guidance of Lai et al., Cainelli et al., and Hwu et al. along with routine experimentation to make the claimed invention with a reasonable expectation of success. The motivation to do so is to reduce the cost of manufacturing nitrooxy-linked diclofenac which has been known for over a decade.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

### **Conclusion**



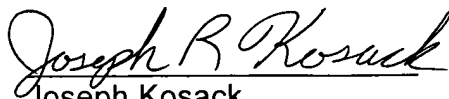
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Claims 1, 6-22, 24 and 39-48 are rejected. Claims 1, 6-22, 24 and 39-48 are objected to.

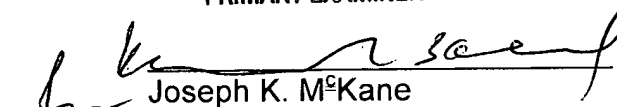
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 5:30 A.M. until 2:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Joseph Kosack  
Patent Examiner  
Art Unit 1626

KAMAL A. CALHOE, F.T.D.  
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